

Notice of Allowability

Application No.

09/226,895

Examiner

Karen A. Canella

Applicant(s)

ROSENBLUM ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to tyhe amendment filed Dec 20, 2006.
2. ☒ The allowed claim(s) is/are 5, 6, 8, 9, 11, 13 and 16-19, renumbered as 2, 1, 3, 46, 5 and 7-10.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


KAREN A. CANELLA
SENIOR EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Landrum on January 12, 2007.

The application has been amended as follows:

In the claims

In claim 5:

The both occurrences of "nephthalenyl" are substituted with ---naphthalenyl---.

Claim 6 was replaced with the following:

6. A method of treating an individual having acute myeloid leukemia, acute promyelocytic leukemia, lymphoma or myeloma, comprising the steps of:

- a) administering to said individual a pharmacologically effective dose of a retinoid which up-regulates the expression of CD38 antigen, followed by
- b) administering to the same individual a pharmacologically effective dose of an immunotoxin directed to CD38,

wherein said retinoid is administered in a dose of from about 0.1 mg/kg to about 2 mg/kg.

Claim 11 has been replaced with the following:

11. A method of treating an individual having acute myeloid leukemia, acute promyelocytic leukemia, lymphoma or myeloma, comprising the steps of:

- a) administering to said individual a pharmacologically effective dose of a retinoid which up-regulates the expression of CD38 antigen, followed by
- b) administering to the same individual a pharmacologically effective dose of an immunotoxin directed to CD38,

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wherein said immunotoxin is administered in a dose of from about 0.05 mg/kg to about 2 mg/kg.

Claim 13 has been replaced by the following:

13. The method of claim 6, wherein said acute promyelocytic leukemia is adriamycin resistant.

Claim 19 has been replaced with the following:

19. The method of claim 11, wherein said acute promyelocytic leukemia is adriamycin resistant.

In claim 16:

The both occurrences of "nephtalenyl" are substituted with ---naphthalenyl---.

In the specification

On page 11, lines 6 and 8, the word "nephtalenyl" is substituted with ---naphthalenyl---.

It is noted that on page 18, example 7, the HL-60 cells which are adriamycin resistant are human acute promyelocytic leukemia cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

1/08/2007


KAREN A. CANELLA
PRIMARY EXAMINEE